

REMARKS

The pending claims in this application are claims 6, 7, 9, 11-13, 16 and 28-31. The Office Action maintained the rejection of claims 6, 7, 9, 11, 12, 13, 16 and 28 under 35 USC 103(a) as being unpatentable over Lohray et al (WO 9741097). The Office Action has further maintained the objection to claims 29-31 as being dependent upon a rejected base claim.

The present invention is concerned with a new pharmaceutical composition with improved stability, particularly in solid dosage forms. The inventors of the present application discovered that when they use excipients which have low water content, the active ingredient and its salts do not decompose in the presence of and in contact with water.

The Office Action appreciates that Lohray et al. does not teach the use of low water content. To remedy that acknowledged difference between the claimed invention and Lohray et al., the Office Action asserts that it would have been obvious to one of ordinary skill in the art to modify the composition in the Lohray et al. reference to employ any form of lactose because Lohray et al. teach the composition comprising lactose in general. The Office Action further asserts that Lohray et al. utilize a cellulose derivative, carboxymethyl cellulose, which has a viable utility as an excipient which is closely related to microcrystalline cellulose and thus one of ordinary skill in the art would expect that compounds so closely related chemically would have the same or essentially the same properties.

Applicants' respectfully traverse this rejection and submit that the Office Action has failed to make a prima facie case of obviousness.

In determining whether a case of prima facie obviousness exists, it is necessary to ascertain whether the prior art teaching would appear to be sufficient to one of ordinary

skill in the art to suggest making the substitution or modification to the cited art to arrived at the claimed invention. 35 U.S.C. § 103 (a) (1999); Graham v. John Deere Co., 383 U.S. 1, 14, 145 USPQ 459, 465 (1966). The mere possibility that the prior art could be modified is not a sufficient basis for a prima facie case of obviousness. See In re Brouwer, 77 F.3d 422, 425, 37 USPQ2d 1663, 1666 (Fed. Cir. 1996); In re Ochaiai, 71 F.3d 1565, 1570, 37 USPQ2d 1127, 1131 (Fed. Cir. 1995). The Office Action must explain why the prior art would have suggested to one of ordinary skill in the art the desirability of the modification. See In re Fritch, 972, F.2d 1260, 1266, 23 USPQ2d 1780, 1783-84 (Fed. Cir. 1992). Further, where the Office Action combines two or more elements, “the question is whether there is something in the prior art as a whole to suggest the desirability, and thus obviousness, of making the combination.” Lindemann Maschinenfabrik GmbH v. American Hoist & Derrick Co., 730 F.2d 1452, 1462, 221 USPQ 481, 488 (Fed. Cir. 1984, (citations omitted) {emphasis added}).

Furthermore, rejections based on §103(a) must rest on a factual basis with the facts being interpreted without hindsight reconstruction of the invention from the prior art. See In re Warner, 379 F.2d 1011, 1017, 154 USPQ 173, 177 (CCPA 19667) cert. denied, 389 U.S. 1057 (1968). The Federal Court has repeatedly cautioned against employing hindsight by using the inventor’s disclosure as a blueprint to reconstruct the claimed invention from the isolated teaching of the prior art. See, e.g., Grain Processing Corp. v. American Maire-Products Co., 640 F.2d 902, 907, 5 USPQ2d 1788, 1792 (Fed. Cir. 1988).

In the present case, the Office Action has not established any convincing reason, suggestion or motivation for modifying Lohray et al. so as to arrive at the claimed subject matter.

At the time the invention was made, excipients were increasingly being recognized for the critical role they play in pharmaceutical products. Pharmaceutical excipients contribute enormously to the efficacy of a product by providing specific special functionalities in formulations. Moreover, the growth of novel forms of delivery

has resulted in an increase in the number of the excipients being used and the development of excipient mixtures and new physical forms to improve their properties.

Applicants have conducted various tests to compare the excipients used in the present invention and those used in the Lohray reference. (See Declaration of Thyge Borup Hjorth dated August 21, 2002, which was previously submitted and response to Office Action mailed August 3, 2004). It is clear from the comparative tests that the excipients of the present invention play a role in the stability of the tablets which is the concern of the present invention. Lohray et al., on the other hand is concerned with disclosing general formulation of its compounds which may be in the form of tablets. However, Lohray does not admit to any deficiency which would lead one to modify such deficiency.

The contention that it would have been obvious to one skilled in the art to modify a reference so as to arrive at the present invention is simply unsupported by the teachings of the prior art. See In re Kotzab, 217 F.3d 1365, 1371, 55 USPQ2d 1313, 1317 (Fed. Cir. 2000). (“[P]articular findings must be made as to the reasons the skilled artisan with no knowledge of the claimed invention, would have selected these components for combination in the manner claimed”). While it is true that the suggestion or motivation to modify a reference may be implicit from the prior art as a whole rather than expressly stated, the Office Action must still provide reasons for finding a limitation to be taught or suggested in the references. Kotzab, 217 F.3d at 1370, 55 USPQ2d at 1316. In this regard, the Office Action has not established why one of ordinary skill in the art would choose to specifically replace the lactone and cellulose nor has the Office Action established why a person of ordinary skill in the art would view Lohray et al. as requiring any correction or modification.

The flaw in the reasoning of the Office Action is that Lohray et al. do not disclose or suggest the desirability for making the tablet more stable by using anhydrous lactose and microcrystalline cellulose as taught in the present invention. Hence, the Office Action has not established the requisite motivation for one of ordinary skill in the art to modify Lohray et al..

In sum, modifying Lohray et al. can only be based upon improper hindsight reasoning. See, W. L. Gore & Associates v. Garlock, Inc., 721 F.2d 1540, 1553, 220 USPQ 303, 312-13 (Fed. Cir. 1983), cert. denied, 469 U.S. 851 (1984) (“To imbue one of ordinary skill in the art with knowledge of the invention in suit, when no prior art reference or references of record convey or suggest that knowledge, is to fall victim to the insidious effect of a hindsight syndrome wherein that which only the inventor taught is used against its teacher.”) In addition, when it is necessary to selectively modify the prior-art reference in order to render obvious a subsequent invention, there must be some reason for the modification other than the hindsight gleaned from the invention itself. There must be some teaching in the prior art as a whole to suggest the desirability, and thus the obviousness of modifying the referenced art. Uniroyal Inc. v. Rudkin-Wiley Corp., 3 USQ2d 1434 (Fed. Cir. 1988)

In the present application, rather than attempting to show how the claimed invention, as a whole, is suggested by the prior art, as is required by the applicable authorities, the Office Action has focused on individual elements or “features” of the claimed invention. However, the Office Action has not explained where the motivation or suggestion for modifying the composition of Lohray et al. is found in the cited reference or for that matter, in any prior art teaching.

With all the different excipients available, the Office Action with regards to the Lohray reference is at most an invitation to experiment. Even if it were "obvious to try" to construct Applicants' claimed invention, which Applicants emphatically do not concede, such an "obvious to try" standard has been repeatedly rejected as an improper basis for a rejection under 35 U.S.C. 103. E.g., In re O'Farrell, 7 USPQ2d 1673, 1681 (Fed.Cir. 1988); In re Fine, 5 USPQ2d 1596, 1599 (Fed. Cir. 1987). However, as was stated in In re Dow Chemical, 5 USPQ2d 1529, 1532 (Fed.Cir. 1988), this is not an appropriate test of obviousness:

"The PTO presents, in essence, an 'obvious to experiment' standard for obviousness. However, selective hindsight is no more applicable to the design of experiments than it is to the combination of prior art

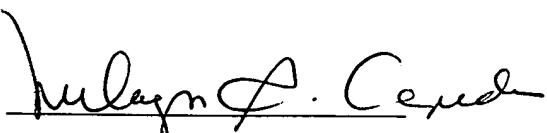
teachings. There must be a teaching or suggestion in the art for selecting the procedure used, other than the knowledge learned from the applicant's disclosure."

The Office Action reliance on Lohray et al. fail absolutely to meet the test set forth in Dow.

Claims 7, 9, 11, 12, 13, 16, 28 and 29-31 depend from claim 6 and define additional limitations to the material. Further, since these claims depend from claim 6 it is believed to that these claim are allowable at least for the same reasons that claim 6 allowable. Applicants therefore requests withdrawal of the rejection of claims 6, 7, 9, 11, 12, 13, 16, and 28-31.

In view of the foregoing remarks, Applicants submits that the pending claims particularly define and patentably distinguish the invention over the art of record, and request that the Rejection be withdrawn and that this case is passed to issuance. Should the Office believe that further issues remain to be resolved it is requested that she telephone the undersigned in order to provide the Applicants with an opportunity to resolve such issues.

Respectfully submitted,



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Date

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